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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,498

01/09/2006

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,498	Applicant(s) ZHANG ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8 and 13-56 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 34-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,13-33 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/29/2009 has been entered.
2. Claims 1-4, 8, and 13-56 are pending; Claims 3-4 and 34-55 stand withdrawn as being drawn to non-elected inventions. Acknowledgement is made of amendment of claim 1 and cancellation of claims 10-12 in Applicants' filing of 6/29/2009. Claims 1-2, 8, 13-33 and 56 are examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-2, 8, 13-33 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites: "other undesirable constituents". However, the specification does not define "undesirable" so the meaning of the phrase is unclear.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Rejection of claims 1, 2, 8, 13-33 and 56 under 35 U.S.C. 103(a) as being unpatentable over Fletcher, Kemshead & Ugelstad, and Rudi, et al. is **withdrawn** in view of amendment of claim 1.
5. Claims 1, 2, 8, 13-33 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berenson, et al. (US 20020058019) view of Kemshead & Ugelstad, and Rudi *et al.* The claims are drawn to a method of cell separation that excludes specific binding pair interaction and includes magnetic microbeads. Further limitations of the basic method specifies the type of cell or virus (claims 2 and 27), the size of the beads (claim 10), modification or lack thereof of the microbead (claim 11), an additional washing step to remove undesirable constituents (claims 13, 31-32 and 56), an additional recovery step (claims 14 and 15), the nature of the sample (claims 16-17 and 27-29), an additional step of recovering a biological material from the target (claims 18-19), the additional step of amplifying recovered oligonucleotide (claim 20), automation of the process (claim 21), absence of a precipitation step (claim 24) or poisonous agent (claim 25), ambient temperature during procedure (claim 26), pH range and presence of anticoagulant (claims 29-30).

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Berenson, et al. teaches a method of separation of monocytes from blood preparations using the well-known property inherent in monocytes to engulf various materials indiscriminately. Of particular note is the teaching that the method taught by Berenson, et al. relies solely on the ability of monocytes engulf the magnetic microbeads rather than a particular functional group. Berenson, et al. does not teach several additional of the limitations outlined above. Kemshead and Ugelstad teach the use of magnetic materials for medical applications. As one of the pioneer inventors of magnetic microbeads, Ugelstad is responsible for ensuring the size homogeneity of polymeric magnetic microbeads and inclusion of derivatized magnetic microbeads further useful in medically relevant treatment and diagnostic methods as well as usefulness in basic medical research.

Kemshead and Ugelstad specifically teach separation methods using magnetic microbeads for a variety of cell types using both non-specific binding (see, for example, section II. Ways of generating magnetic cells) and specific binding partners (see, for example, section III. Targeting 'magnetic material' to cells).

Thus, the combination of Berenson, et al. and Kemshead and Ugelstad teach that several types of cells can be separated and enriched from model environmental and clinical samples using magnetic polystyrene beads. Rudi, et al. teaches a method of using magnetic microbeads to sequentially separate bacteria from environmental samples and amplify separated DNA using the same magnetic microbeads.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Berenson, et al. with the various washing and organelle preparation techniques as taught by Kemshead and Ugelstad and/or Rudi, et al. The skilled artisan would have been motivated to do so because of the nonspecific incorporation of beads by monocytes as taught by Berenson, et al. and the rapidity of magnetic bead separation as taught by Kemshead and Ugelstad and/or Rudi, et al. especially when attempting isolation from rich sources of cells such as blood, cell cultures and/or dilute environmental sources. There would have been a reasonable expectation of success, given well-known phagocytic properties of monocytes as taught by Berenson, et al. and the general utility of magnetic bead separation methods as taught by many researchers especially including Kemshead and Ugelstad and/or Rudi, et al.

Conclusion

6. No claims are allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS